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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Robert David Darrow et al.

Serial No.: 10/064,749

Filed: August 13, 2002

For: MEDICAL DEVICE POSITIONING
SYSTEM AND METHOD

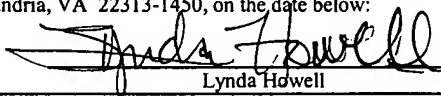
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Group Art Unit: 3737

Examiner: Joel Lamprecht

Atty. Docket: RD27658-1/YOD
GERD:0522

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July 20, 2007	
Date	Lynda Howell

APPEAL BRIEF PURSUANT TO 37 C.F.R. §§ 41.31 AND 41.37

This Appeal Brief is being filed in furtherance to the Notice of Appeal mailed on May 16, 2007, and received by the Patent Office on May 21, 2007.

The Commissioner is authorized to charge the requisite fee of \$500.00, and any additional fees which may be necessary to advance prosecution of the present application, to Account No. 07-0868, Order No. RD27658-1/YOD (GERD:0522).

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F. **Ground of Rejection No. 6:**

The Examiner rejected claims 2, 11, 12, 20 and 21 under 35 U.S.C. § 103(a) as being unpatentable over Dumoulin '165 in view of Dumoulin '635 and further in view of Panescu.

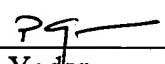
As stated above, Dumoulin '635 alone or in combination with Dumoulin '165 does not teach, suggest or disclose each and every aspect of Appellants' invention as claimed in the independent claims 1 and 13. Claims 2, 11, 12, 20 and 21 depend directly or indirectly from allowable claim 1 and 13, and are allowable by virtue of such dependency, as well as for the subject matter they separately recite. Thus, it is respectfully requested that the rejection of claims 2, 11, 12, 20 and 21 under 35 U.S.C. §103(a) be reversed.

Conclusion

Appellants respectfully submit that all pending claims are in condition for allowance. However, if the Examiner or Board wishes to resolve any other issues by way of a telephone conference, the Examiner or Board is kindly invited to contact the undersigned attorney at the telephone number indicated below.

Respectfully submitted,

Date: 2/20/2007



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1. **REAL PARTY IN INTEREST**

The real party in interest is General Electric Company, the Assignee of the above-referenced application by virtue of the Assignment to General Electric Company by Robert David Darrow and Charles Lucian Dumoulin recorded at reel 012979, frame 0157, and dated August 13, 2002. Accordingly, General Electric Company, as Assignee of the above-referenced application, will be directly affected by the Board's decision in the pending appeal.

2. **RELATED APPEALS AND INTERFERENCES**

Appellants are unaware of any other appeals or interferences related to this Appeal. The undersigned is Appellants' legal representative in this Appeal.

3. **STATUS OF CLAIMS**

Claims 1, 2, 4-17 and 19-32 are currently pending, are currently under final rejection and, thus, are the subject of this Appeal.

4. **STATUS OF AMENDMENTS**

Appellants have not submitted any amendments subsequent to the Final Office Action mailed on January 22, 2007. Consequently, there are no outstanding amendments to be considered by the Board.

5. **SUMMARY OF CLAIMED SUBJECT MATTER**

The present invention relates generally to systems for image guided interventional medical procedures in which a device is inserted into a body during imaging. *See* Application (published U.S. Patent Application No. 2004/0034297), page 1, paragraph 2. More particularly, in certain embodiments, the invention relates to systems which assist in executing the diagnostic and interventional procedures such as assisting in the positioning of the device during the procedures. *See id.*

The Application contains four independent claims, namely, claims 1, 13, 23 and 32, all of which are the subject of this Appeal. The subject matter of these claims is summarized below.

With regard to the aspect of the invention set forth in independent claim 1, discussions of the recited features of claim 1 can be found at least in the below cited locations of the specification and drawings. Claim 1 relates to a medical device positioning system for use during a medical procedure on a subject (*e.g.*, 100) performed during imaging. The system includes a medical device (*e.g.*, 150) adapted for internal use within the subject (*e.g.*, 100) for performing the medical procedure, an imaging device (*e.g.*, 120) for acquiring image data of a region of interest within the subject (*e.g.*, 100), and a medical device monitoring and positioning subsystem (*e.g.*, 210) for monitoring position of the medical device (*e.g.*, 150) relative to a target region of interest within the subject (*e.g.*, 100), for providing feedback to an interface unit (*e.g.*, 123), and for repositioning the medical device (*e.g.*, 150) within the target region of interest without moving the subject (*e.g.*, 100) when the position of the medical device (*e.g.*, 150) deviates from the target region of interest. *See, e.g., id.* at page 2, paragraph 24; *see also*, FIG. 1, pages 2-3, paragraphs 26-28, and pages 3-4, paragraphs 30-33.

With regard to the aspect of the invention set forth in independent claim 13, discussions of the recited features of claim 13 can be found at least in the below cited locations of the specification and drawings. Claim 13 also relates to a medical device positioning system for use during a medical procedure on a subject (*e.g.*, 100) performed during imaging. The system includes a medical device (*e.g.*, 150) adapted for internal use within the subject (*e.g.*, 100) for performing the medical procedure, an imaging device (*e.g.*, 120) for acquiring image data of a region of interest within the subject (*e.g.*, 100), and a tracking device (*e.g.*, 151) for tracking a location of the medical device (*e.g.*, 150). The system further includes a processor (*e.g.*, 121) coupled to the imaging device (*e.g.*, 120) and the tracking device (*e.g.*, 151) for generating images of the region of interest with a visual representation of the medical device (*e.g.*, 150) superimposed on the

images. The processor (*e.g.*, 121) is further adapted to monitor a position of the medical device (*e.g.*, 150) relative to the region of interest, the processor (*e.g.*, 121) responding to change in the position by repositioning the medical device (*e.g.*, 150) within the target region of interest without moving the subject (*e.g.*, 100), and providing feedback to an interface (*e.g.*, 123). *See, e.g., id.* at page 2, paragraph 24; *see also*, FIG. 1, pages 2-3, paragraphs 26-28, and pages 3-4, paragraphs 30-33.

With regard to the aspect of the invention set forth in independent claim 23, discussions of the recited features of claim 23 can be found at least in the below cited locations of the specification and drawings. Claim 23 relates to a method for positioning a medical device (*e.g.*, 150). The method includes generating at least one image of a region of interest of a subject (*e.g.*, 100) including a representation of a medical device (*e.g.*, 150) superimposed in the image, monitoring a position of the medical device (*e.g.*, 150) relative to a target region of interest within the subject (*e.g.*, 100), providing feedback to an interface (*e.g.*, 123) upon detection of a change in position of the medical device (*e.g.*, 150) relative to the target region, and responding to the change by repositioning the medical device (*e.g.*, 150) within the target region of interest without moving the subject (*e.g.*, 100). *See, e.g., id.* at page 2, paragraph 24; *see also*, FIG. 1, pages 2-3, paragraphs 26-28, and pages 3-4, paragraphs 30-33.

With regard to the aspect of the invention set forth in independent claim 32, discussions of the recited features of claim 32 can be found at least in the below cited locations of the specification and drawings. Claim 32 relates to a medical device positioning system for use during a medical procedure on a subject (*e.g.*, 100) performed during imaging. The system includes a medical device (*e.g.*, 150) adapted for internal use within the subject (*e.g.*, 100) for performing the medical procedure, an imaging device (*e.g.*, 120) for acquiring image data of a region of interest within the subject (*e.g.*, 100), and a medical device monitoring and positioning subsystem (*e.g.*, 210) for monitoring position of the medical device (*e.g.*, 150) relative to a target region of interest within the subject (*e.g.*, 100), for providing feedback to an interface unit (*e.g.*, 123), and

for responding to motion of at least one of the medical device (*e.g.*, 150) or the subject (*e.g.*, 100) in a predetermined fashion when the position of the medical device (*e.g.*, 150) deviates from the target region of interest. The predetermined response comprises at least one of terminating therapy, repositioning the medical device within the target region of interest without moving the subject (*e.g.*, 100), activating an audio or text advisory feedback to the interface unit (*e.g.*, 123), or a combination thereof. *See, e.g., id.* at page 2, paragraph 24; *see also*, FIG. 1, pages 2-3, paragraphs 26-28, and pages 3-4, paragraphs 30-33.

A benefit of the invention, as recited in these claims, is the ability to monitor the movement of medical device with respect to target region of interest and control the medical procedure based on the monitoring. For example, as described in the specification, controlling the medical procedure may include terminating the procedure, repositioning the medical device within the target region of interest without moving the subject and/or activating an audio or text advisory feedback to the interface unit. Thus, the disclosed technique improves the efficiency and success rate of the medical procedure. *See, e.g., id.* at pages 3-4, paragraphs 30-33.

The invention is thus clearly different and distinct from the prior art, as discussed below.

6. **GROUND OF REJECTION TO BE REVIEWED ON APPEAL**

First Ground of Rejection for Review on Appeal:

Appellants respectfully urge the Board to review and reverse the rejection of claims 1, 2, 4-10, 13-17, 19, 22-31 and 32 under 35 U.S.C. § 102(b) as being anticipated by Dumoulin et al., U.S. Patent No. 5,251,635 (hereinafter “Dumoulin ‘635”).

Second Ground of Rejection for Review on Appeal:

Appellants respectfully urge the Board to review and reverse the rejection of claim 32 under 35 U.S.C. § 103(a) as being unpatentable over Dumoulin ‘635.

Third Ground of Rejection for Review on Appeal:

Appellants respectfully urge the Board to review and reverse the rejection of claims 2, 11, 12, 20 and 21 under 35 U.S.C. § 103(a) as being unpatentable over Dumoulin '635 in view of Panescu et al., U.S. Patent No. 5,916,163 (hereinafter "Panescu").

Fourth Ground of Rejection for Review on Appeal:

Appellants respectfully urge the Board to review and reverse the rejection of claims 6, 17, and 24 under 35 U.S.C. § 103(a) as being unpatentable over Dumoulin '635 in view of Twiss et al., U.S. Patent No. 5,375,596 (hereinafter "Twiss").

Fifth Ground of Rejection for Review on Appeal:

Appellants respectfully urge the Board to review and reverse the rejection of claims 1, 2, 4-10, 13-17, 19, and 22-31 under 35 U.S.C. § 103(a) as being unpatentable over Dumoulin et al., U.S. Patent No. 5,211,165 (hereinafter "Dumoulin '165") in view of Dumoulin '635.

Sixth Ground of Rejection for Review on Appeal:

Appellants respectfully urge the Board to review and reverse the rejection of claims 2, 11, 12, 20 and 21 under 35 U.S.C. § 103(a) as being unpatentable over Dumoulin '165 in view of Dumoulin '635 and further in view of Panescu.

7. **ARGUMENT**

As discussed in detail below, the Examiner has improperly rejected the pending claims. Further, the Examiner has misapplied long-standing and binding legal precedents and principles in rejecting the claims under Sections 102 and 103. Accordingly, Appellants respectfully request full and favorable consideration by the Board, and reversal of the outstanding rejections. Appellants strongly believe that claims 1, 2, 4-17, and 19-32 are currently in condition for allowance.

A. **Ground of Rejection No. 1:**

The Examiner rejected each of the independent claims 1, 13, 23 and 32 under 35 U.S.C. §102(b) as being anticipated by Dumoulin '635. A *prima facie* case of anticipation under 35 U.S.C. § 102 requires a showing that each limitation of a claim is found in a single reference, practice or device. *In re Donohue*, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985). Appellants respectfully assert that the present invention, as recited in independent claims 1, 13, 23 and 32 is patentable over the Dumoulin '635 reference.

Independent claims 1, 13, 23 and 32 recite, in generally similar language, *repositioning the medical device within the target region of interest without moving the subject*. Independent claim 32 further recites *terminating therapy, activating an audio or text advisory feedback to the interface unit, or a combination thereof*.

Dumoulin '635 discloses stereoscopic tracking of the three-dimensional position and orientation of an invasive device within a subject without using X-rays. However, *Dumoulin '635 fails to disclose or suggest positioning of the medical device within the target region of interest without moving the subject*. Appellants respectfully submit that the positioning of the medical device within the target region of interest may be achieved in the present invention by moving the medical device itself via a medical device positioning subsystem or a processor.

The Examiner, in his response to arguments, stated that Dumoulin '635 discloses a device for repositioning a medical device within the target region of interest without moving the subject. However, *Dumoulin '635 actually discloses automatic placement and alignment of the subject by use of a support arm within a desired region around invasive device*. See, column 7, lines 24-27. Clearly, *automatic placement and alignment of the subject by use of a support arm within a desired region around an invasive device* is not the same as *positioning a medical device within the target region of interest without moving the subject*.

The Examiner, in his response to arguments, further stated that the imaging device disclosed in Dumoulin '635 is capable of both translational and rotational motion to facilitate any modifications in the area to be imaged. It is thus understood that the subject of the procedure would not be required to move during tracking and imaging. *Even if this were true, Appellants respectfully submit that tracking and imaging a medical device within a subject without moving the subject cannot be interpreted as positioning a medical device within the target region of interest without moving the subject.* Dumoulin '635 is clearly incapable of, and did not contemplate such positioning.

The Examiner, in his response to arguments, further stated that Figure 1 of Dumoulin '635 (erroneously referred to as the current specification) clearly shows the support arm for the imaging device moving and that the support arm is not connected to the support table at all. The Examiner then made a logical jump and stated that the support table (labeled 110) and the subject (labeled 112) are not moved; rather the support arm and the imaging apparatus seem to move to enable better viewing of the area of interest (column 7, lines 24-37). The Examiner further pointed to Dumoulin '635, column 27-30 and stated that "[t]he calculated position of the invasive device from tracking computer is supplied to a positioning means which controls the position and orientation of the support arm in relation to support table" would imply that the moving parts (support arm) move in relation to the table and not the other way round. *Even if this were true, Appellants respectfully assert that positioning means which control the position and orientation of support arm in relation to support table cannot be interpreted as medical device positioning subsystem or processor that positions a medical device within the target region of interest.* Moreover, Dumoulin '635 clearly teaches *automatic placement and alignment of the subject by use of a support arm* within a desired region around invasive device and not the other way round. *See*, column 7, lines 24-27.

The Examiner further added that in the claims of Dumoulin '635, specifically claims 3-5, Dumoulin discloses at least a device that is well known in the art to be

capable of being moved relative to a patient without necessitating the movement of the patient (such as guide wire). The Examiner further stated that as is inherent with a device attached to a guide wire or simply a guide wire itself, the surgeon places and adjusts the position of the wire or device relative to the patient without moving the patient, based on the feedback from the imaging/locating device. *Again, even if this were true, Appellants respectfully submit that manually positioning an invasive device (by a surgeon) while looking at the superimposed position of the invasive device in an X-ray image of the subject cannot be interpreted as positioning the invasive device through use of a medical device positioning means or a processor within the target region of interest.*

Additionally, *the present application discloses a positioning subsystem that is configured to respond to motion of at least one of the medical device or the subject in a predetermined or pre-programmed fashion when the position of the medical device deviates from the target region of interest. See, Application, page 10, lines 7-12; see also, page 9, lines 12-16.* The Examiner argued that Dumoulin '635 teaches a monitoring subsystem that is responsive to the movement of the medical device relative to the target region within the subject by activating the imaging system to automatically move and acquire new/additional images without moving the subject. The Examiner further argued that the monitoring subsystem disclosed in Dumoulin '635 provides advisory feedback to the interface unit when the medical device deviates from a target position, via a visual icon representing the position of the device. Additionally, the Examiner argued that the feedback provided to the interface can be used to navigate the device to a region of interest.

Appellants, here again, respectfully submit that Dumoulin '635 does not disclose or suggest a medical device monitoring **and positioning** subsystem or a processor as recited in the claims. The monitoring subsystem disclosed in Dumoulin '635 is configured only to track the medical device within the subject by repeated acquisition of images. Dumoulin '635 further discloses a superimposed visual icon on the X-ray image of the subject to represent the tracked medical device. Appellants respectfully submit

that Dumoulin '635 does not disclose the claimed predetermined or pre-programmed response such as terminating therapy or repositioning the medical device within the target region of interest without moving the subject (as argued above) or activating an audio or a text advisory feedback to the interface unit.

Further, the Examiner argued that Dumoulin '635 discloses positioning a medical device within the target region of interest without moving the subject as a predetermined response. However, as stated above, Dumoulin '635 discloses *automatic placement and alignment of the subject by use of a support arm within a desired region around an invasive device based on the feedback, and not navigating or repositioning the "medical device" during the medical procedure without moving the subject based on the feedback to the interface unit.*

Appellants, therefore, believe that in absence of the positioning subsystem that is configured to respond in a predetermined or pre-programmed fashion as described above, the present invention, as recited in the claims, is not enabled by Dumoulin '635.

At least because Dumoulin '635 fails to disclose or suggest a positioning subsystem that is configured to reposition the medical device within the target region of interest without moving the subject, as claimed, the reference cannot support a *prima facie* case of anticipation of claims 1, 13, 23 and 32. Claims 2, 4-10, 14-17, 19, 22 and 24-31 depend directly or indirectly from claims 1, 13 and 23 respectively. Accordingly, Appellants submit that claims 2, 4-10, 14-17, 19, 22 and 24-31 are allowable by virtue of their dependency from allowable base claims. Appellants also submit that the dependent claims are further allowable by virtue of the subject matter they separately recite. Thus, it is respectfully requested that the rejection of claim 1, 2, 4-10, 13-17, 19, and 22-32 under 35 U.S.C. §102(b) be reversed.

B. Ground of Rejection No. 2:

The Examiner rejected claim 32 under 35 U.S.C. § 103(a) as being unpatentable over Dumoulin '635. Appellants respectfully traverse this rejection.

As stated above, independent claim 32 recites *terminating therapy, repositioning the medical device within the target region of interest without moving the subject, activating an audio or text advisory feedback to the interface unit, or a combination thereof*.

The Examiner failed to apply a reference that includes *all* of the recited features of claim 32. Appellants respectfully submit that Dumoulin '635 does not describe *any claimed predetermined or pre-programmed responses such as terminating therapy or repositioning the medical device within the target region of interest without moving the subject (as argued above) or activating an audio or a text advisory feedback to the interface unit whatsoever*. Thus, Dumoulin '635 does not teach or suggest all of the recitations of the claim 32.

MPEP 2143.03 states that,

[t]o establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.

Appellants respectfully submit that, as stated above, there is no teaching or suggestion of *any claimed predetermined or pre-programmed responses* in Dumoulin '635. In view of the forgoing considerations, Appellants contend that the reference fails to establish a *prima facie* case of obviousness of claim 32. Claim 32 is therefore believed to be clearly patentable over the cited reference.

C. Ground of Rejection No. 3:

The Examiner rejected claims 2, 11, 12, 20 and 21 under 35 U.S.C. § 103(a) as being unpatentable over Dumoulin '635 in view of Panescu.

As discussed above, Dumoulin '635 does not teach, suggest or disclose each and every aspect of Appellants' invention as recited in independent claims 1 and 13. Claims 2, 11, 12, 20 and 21 depend directly or indirectly from allowable claims 1 and 13, and are allowable by virtue of such dependency, as well as for the subject matter they separately recite. Thus, it is respectfully requested that the rejection of claims 2, 11, 12, 20 and 21 under 35 U.S.C. §103(a) be reversed.

D. **Ground of Rejection No. 4:**

The Examiner rejected claims 6, 17, and 24 under 35 U.S.C. § 103(a) as being unpatentable over Dumoulin '635 in view of Twiss.

As discussed above, Dumoulin '635 does not teach, suggest or disclose each and every aspect of Appellants' invention as recited in independent claims 1, 13 and 23. Claims 6, 17, and 24 depend directly or indirectly from allowable claims 1, 13 and 23, and are allowable by virtue of such dependency, as well as for the subject matter they separately recite. Thus, it is respectfully requested that the rejection of claims 6, 17, and 24 under 35 U.S.C. §103(a) be reversed.

E. **Ground of Rejection No. 5:**

The Examiner rejected claims 1, 2, 4-10, 13-17, 19, and 22-31 under 35 U.S.C. § 103(a) as being unpatentable over Dumoulin '165 in view of Dumoulin '635.

For the same reasons set forth above, Dumoulin '635 even in combination with Dumoulin '165 does not teach, suggest or disclose each and every aspect of the invention claimed in independent claims 1, 13 and 23. That is, Dumoulin '165 does not provide the positioning discussed above that is wholly absent from Dumoulin '635. Claims 2, 4-10, 14-17, 19, 22 and 24-31 depend directly or indirectly from claims 1, 13 and 23 and are allowable by virtue of such dependency, as well as for the subject matter they separately recite. Thus, it is respectfully requested that the rejection of claims 1, 2, 4-10, 13-17, 19, and 22-31 under 35 U.S.C. §103(a) be reversed.

8. **APPENDIX OF CLAIMS ON APPEAL**

Listing of Claims:

The following listing of the claims is provided in accordance with 37 C.F.R. §1.121:

1. A medical device positioning system for use during a medical procedure on a subject performed during imaging, the system comprising:
 - a medical device adapted for internal use within the subject for performing the medical procedure;
 - an imaging device for acquiring image data of a region of interest within the subject; and
 - a medical device monitoring and positioning subsystem for monitoring position of the medical device relative to a target region of interest within the subject, for providing feedback to an interface unit, and for repositioning the medical device within the target region of interest without moving the subject when the position of the medical device deviates from the target region of interest.
2. The system of claim 1 wherein the medical device monitoring and positioning subsystem is adapted to receive configuration information corresponding to the medical device and wherein the configuration information comprises at least one of three-dimensional (3D) coordinates of the device, tracking method information corresponding to the medical device, physical dimensions of the device and a model representation of the device.
4. The system of claim 1 wherein the medical device monitoring and positioning subsystem is further adapted for responding to motion of at least one of the medical device or the subject in a predetermined fashion, wherein the predetermined response comprises at least one of terminating therapy, activating the imaging device to

acquire a new image, activating an advisory message to the interface unit, or a combination thereof.

5. The system of claim 1 wherein the medical device monitoring and positioning subsystem is further adapted for providing advisory feedback to the interface unit.

6. The system of claim 5 wherein the advisory feedback comprises at least one of a visual icon representing position of the device, a text message and an audio advisory.

7. The system of claim 1 further comprising a tracking device for tracking a location of the medical device.

8. The system of claim 1 wherein the imaging device comprises at least one of a magnetic resonance imaging (MRI) scanner, a computed tomography (CT) scanner, a X-ray device, a Positron Emission Tomography (PET) system and an ultrasound scanner.

9. The system of claim 1 wherein the medical device comprises at least one of a biopsy needle guide, an invasive probe, an ablation device, a laparoscope and a therapeutic laser.

10. The system of claim 1 wherein the interface is further adapted to respond to operator input of coordinates marking a desired target position for the medical device.

11. The system of claim 2 wherein the medical device configuration information comprises information corresponding to a plurality of medical device types and includes a visual representation of the medical device for superimposing on the images based on the device configuration information for a selected medical device.

12. The system of claim 11 wherein the visual representation of the medical device is a wire-frame model of the medical device.

13. A medical device positioning system for use during a medical procedure on a subject performed during imaging, the system comprising:

a medical device adapted for internal use within the subject for performing a medical procedure;

an imaging device for acquiring image data of a region of interest within the subject;

a tracking device for tracking a location of the medical device; and

a processor coupled to the imaging device and the tracking device for generating images of the region of interest with a visual representation of the medical device superimposed on the images and the processor is further adapted to monitor a position of the medical device relative to the region of interest, the processor responding to change in the position by repositioning the medical device within the target region of interest without moving the subject and providing feedback to an interface.

14. The system of claim 13 wherein the imaging device comprises at least one of a magnetic resonance imaging (MRI) scanner, a computed tomography (CT) scanner, a X-ray device, a Positron Emission Tomography (PET) system and an ultrasound scanner.

15. The system of claim 13 wherein the medical device comprises at least one of a biopsy needle guide, an invasive probe, an ablation device, a laparoscope and a therapeutic laser.

16. The system of claim 13 wherein the interface is coupled to the processor for displaying the images representing the region of interest and the visual representation of the medical device, the interface being for use in positioning the medical device during the medical procedure and being further adapted to respond to movement of the medical device in real-time.

17. The system of claim 13 wherein the feedback provided comprises at least one of a visual icon representing position of the device, a text message, and an audio advisory.

19. The system of claim 13 wherein the processor is further adapted to provide an advisory response when the medical device deviates from a specified target position.

20. The system of claim 13 wherein the processor further includes medical device configuration information corresponding to a plurality of medical device types and wherein the visual representation of the medical device on the images is based on the device configuration information for a selected medical device.

21. The system of claim 20 wherein the visual representation of the medical device is a wire-frame model of the medical device.

22. The system of claim 13 wherein the processor is further adapted to respond in a predetermined fashion if the medical device position deviates by a specified distance from the target region of interest and wherein the predetermined response comprises at least one of terminating therapy, activating the imaging device to acquire a new image, activating an advisory message to the interface unit, or a combination thereof.

23. A method for positioning a medical device comprising:
generating at least one image of a region of interest of a subject including a representation of a medical device superimposed in the image;
monitoring a position of the medical device relative to a target region of interest within the subject; and
providing feedback to an interface upon detection of a change in position of the medical device relative to the target region and responding to the change by repositioning the medical device within the target region of interest without moving the subject.

24. The method of claim 23 wherein the feedback comprises at least one of a first visual icon representing position of the device and a second visual icon representing the target region of interest, a text message, an audio advisory and a response to the change in a predetermined fashion.

25. The method of claim 24 wherein the predetermined response comprises at least one of terminating therapy, activating the imaging device to acquire a new image, activating an advisory message to the interface unit, or a combination thereof.

26. The method of claim 23 wherein the interface is adapted to respond to operator input of coordinates marking a target position of the medical device.

27. The method of claim 23 wherein image data is acquired using of at least one of a magnetic resonance imaging (MRI) scanner, a computed tomography (CT) scanner, a X-ray device, a Positron Emission Tomography (PET) system and an ultrasound scanner.

28. The method of claim 23 wherein the feedback is used for navigating the medical device to a target region of interest.

29. The system of claim 1 wherein the feedback is used for navigating the medical device during the medical procedure.

30. The system of claim 13 wherein the feedback is used for navigating the medical device during the medical procedure.

31. The system of claim 13 wherein the interface is further adapted to respond to operator input of coordinates marking a target position of the medical device.

32. A medical device positioning system for use during a medical procedure on a subject performed during imaging, the system comprising:

a medical device adapted for internal use within the subject for performing the medical procedure;

an imaging device for acquiring image data of a region of interest within the subject; and

a medical device monitoring and positioning subsystem for monitoring position of the medical device relative to a target region of interest within the subject, for providing feedback to an interface unit, and for responding to motion of at least one of the medical device or the subject in a predetermined fashion when the position of the medical device deviates from the target region of interest, wherein the predetermined response comprises at least one of terminating therapy, repositioning the medical device within the target region of interest without moving the subject, activating an audio or text advisory feedback to the interface unit, or a combination thereof.

9. **EVIDENCE APPENDIX**

None.

10. **RELATED PROCEEDINGS APPENDIX**

None.